

Williams, Keturah (NIH/NEI) [E]

From: Shuyuan Yao [REDACTED]
Sent: Saturday, February 20, 2010 11:15 AM
To: Williams, Keturah (NIH/NEI) [E]
Cc: Sheng Ding; kang zhang; Amy and John Buono
Subject: Re: Grant Number: 1 R43 EY 020711 - 01 PI: Shuyuan Yao
Follow Up Flag: Follow up
Flag Status: Red
Attachments: Other Support Example.pdf; Detailed Budget Forms.pdf; Evaluation of Financial Management Systems Questionnaire.pdf; Protocol S09025 (Zhang) Approval.pdf; CalCyte Cover Letter 020711.pdf; detailed budget_020711.pdf; fee_acceptance.pdf; othersupport_Yao.pdf; Protocol S08207 (Zhang) Approval.pdf; SBIR verification_020711.pdf

Dear Keturah,

Attached please find the required documents for grant application 1R34EY020711-01. We have all the documents except the Evaluation of Financial Management Systems Questionnaire. Our financial personal are working on it and will send it to you as quick as they can. Please let me know if you need further information.

Thanks sincerely,

Shuyuan Yao
 CalCyte Inc.
 [REDACTED]

On Wed, Feb 17, 2010 at 1:46 PM, Williams, Keturah (NIH/NEI) [E] <williamskt@nei.nih.gov> wrote:
 Good Afternoon Dr. Yao,

Thank you for submitting the requested documents. However, the following information still needs to be addressed:

- 1) **Updated Other Support:** Please follow the attached format.
- 2) **IACUC:** You can use UCSD's IACUC to approve your protocol. However, the IACUC approval MUST state the title of your project.
- 3) **Detailed Budget:** I have attached detailed budget forms that you should complete for the subcontract.
- 4) **Evaluation of Financial Management Systems Questionnaire:** Please complete the attached questionnaire.
- 5) **Fixed Fee:** NIH allows a 7% fixed fee for Phase I and II SBIR/STTR applications. Please provide in writing whether you wish to either waive or accept this fee.

Please email these documents to me as soon as possible.

Let me know if you have any questions or concerns.

Thanks,

Keturah Williams, M.S.
 Grants Management Specialist
 Grants Management Branch
 National Eye Institute
 301-451-2020 (phone)
 301-496-9997 (fax)
williamskt@nei.nih.gov

From: Shuyuan Yao [mailto: [REDACTED]]
Sent: Wednesday, February 10, 2010 1:29 PM
To: Williams, Keturah (NIH/NEI) [E]
Cc: Sheng Ding; kang zhang
Subject: Re: Grant Number: 1 R43 EY 020711 - 01 PI: Shuyuan Yao

Dear Ms. Williams,

Please check my answers for your requested documents in the following text.

Sincerely,


Shuyuan Yao

CalCyte Inc.
[REDACTED]


Grant Number: 1 R43 EY 020711 - 01

 **Tax Identification (W-9):**


A: we will ask our financial personal provide you the W-9 form soon.

 **Updated Other Support for ALL Key Personnel including Level of Effort for each individual on each research project:**

A: all the information are up to date.

 **Animals:** The Office of Laboratory Animal Welfare (OLAW) will negotiate a Single Project Assurance for this application. Information regarding this process can be found at <http://grants.nih.gov/grants/olaw/olaw.htm>. Once NEI receives the IACUC approval, this process will begin.

A: we in the process to get the LACUC approval.


 **IACUC:** Please provide a copy of the Institutional Animal Care and Use Committee (IACUC) Approval.

2/25/2010


A: We are in the process to get the LACUC approval. But, we are planning to outsource the animal experiment to Dr. Kang Zhang Lab in UCSD. Can we use USCD IACUC in stead?

 **Checklist:** Please provide a completed Checklist.
<http://grants1.nih.gov/grants/funding/phs398/phs398.html>

A: the Checklist file in the application is completed.


 **Detailed budget:** The detailed budget includes \$5,000 in subcontract costs to the University of California, San Diego; however, a detailed budget for UCSD was not included in the grant application. Please submit a detailed budget for the subcontract to UCSD.

A:The \$5,000 subcontract cost to UCSD is for the animal model experiments. We plan to test the developed cells in 2 animal models and use 30 mice for each model. The cost includes animal fee, animal housing fee, animal operation, monitoring, caring and analysis, etc.


 **Audit:** Per the regulations, a commercial organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it expended \$500,000 or more under HHS awards and **at least one award is an HHS grant or subgrant**. Therefore, the organization must have one grant or subgrant in order to be required to obtain a non-federal audit, but other HHS awards are included in the threshold calculations and the scope of the audit. (See [threshold calculation examples](#).)

<http://www.gao.gov/govaud/ybk01.htm> <http://www.whitehouse.gov/OMB/circulars/a133/a133.html>
<http://ocm.od.nih.gov/dfas/faqforprofitaudits.htm>


A: No applicable.

 **Evaluation of Financial Management Systems Questionnaire:** See highlighted link in the "Financial & Business Requirements" attachment for the form. The attachment also states what the requirements are in regards to financial and business management systems for SBIR and STTR awardees.

A). I have read it.

 **Verification Statement:** Please complete and sign the attached "Verification Statement".

A: See signed attachment.

 **Scientific Fraud Assurance:** The Office of Scientific Integrity will be contacting you shortly to establish a Misconduct Assurance.

A: Done.

✓ **NIH Commons:** NIH is moving toward electronic files and communication. In order to help facilitate this, please use e-mail and the NIH ERA Commons <https://commons.era.nih.gov/commons/> as much as possible. Please remember that all e-mail correspondence must be sent by the business official.

A: Done.

On Wed, Jan 27, 2010 at 11:23 AM, Williams, Keturah (NIH/NEI) [E] <williamskt@nei.nih.gov> wrote:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

National Eye Institute

Division of Extramural Research

Grants Management Branch

5635 Fishers Lane

Suite 1300, MSC-9300

Rockville, MD 20892-9300

January 27, 2010

Grant Number: 1 R43 EY 020711 - 01

Dear Ms. Amy Buono,

The above-referenced (SBIR/STTR) competing application has been submitted to the National Eye Institute. This application is among those from which final funding selection are being considered for award. **However, please note that no funding decision has been made at this time.** In order to complete our administrative review of this application, the following documentation must be submitted. Please be aware that all information regarding the (SBIR/STTR) program can be found on the SBIR/STTR Omnibus Solicitations website at <http://grants.nih.gov/grants/funding/sbir.htm>.

2/25/2010

✓ **Tax Identification (W-9):** Provide your organization's W-9 form so that we can establish your organization in the NIH Grants Database. Your Tax ID will become your Entity Identification Number (EIN) in the NIH business systems.

✓ **Updated Other Support for ALL Key Personnel including Level of Effort for each individual on each research project:** All financial resources as defined in the PHS grant application kit.
<http://grants1.nih.gov/grants/funding/phs398/phs398.html>

✓ **Animals:** The Office of Laboratory Animal Welfare (OLAW) will negotiate a Single Project Assurance for this application. Information regarding this process can be found at
<http://grants.nih.gov/grants/olaw/olaw.htm>. Once NEI receives the IACUC approval, this process will begin.

✓ **IACUC:** Please provide a copy of the Institutional Animal Care and Use Committee (IACUC) Approval.

✓ **Checklist:** Please provide a completed Checklist.
<http://grants1.nih.gov/grants/funding/phs398/phs398.html>

✓ **Detailed budget:** The detailed budget includes \$5,000 in subcontract costs to the University of California, San Diego; however, a detailed budget for UCSD was not included in the grant application. Please submit a detailed budget for the subcontract to UCSD.

✓ **Audit:** Per the regulations, a commercial organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it expended \$500,000 or more under HHS awards and **at least one award is an HHS grant or subgrant**. Therefore, the organization must have one grant or subgrant in order to be required to obtain a non-federal audit, but other HHS awards are included in the threshold calculations and the scope of the audit. (See [threshold calculation examples](#).)

<http://www.gao.gov/govaud/ybk01.htm> <http://www.whitehouse.gov/OMB/circulars/a133/a133.html>
<http://ocm.od.nih.gov/dfas/faqforproftaudits.htm>

✓ **Evaluation of Financial Management Systems Questionnaire:** See highlighted link in the "Financial & Business Requirements" attachment for the form. The attachment also states what the requirements are in regards to financial and business management systems for SBIR and STTR awardees.

✓ **Verification Statement:** Please complete and sign the attached "Verification Statement".

- ✓ **Scientific Fraud Assurance:** The Office of Scientific Integrity will be contacting you shortly to establish a Misconduct Assurance.
- ✓ **NIH Commons:** NIH is moving toward electronic files and communication. In order to help facilitate this, please use e-mail and the NIH ERA Commons <https://commons.era.nih.gov/commons/> as much as possible. Please remember that all e-mail correspondence must be sent by the business official.

This link will take you to NIH Welcome Wagon <http://grants.nih.gov/grants/funding/welcomewagon.htm>. Such information as payment procedures, policies, requirements, and standards can be found there. The intent of this document is to highlight key requirements, provide referrals to important sources of information, and identify NIH, Public Health Service (PHS) and Department of Health and Human Services (HHS) offices that have responsibility for certain administrative functions. Information available through these resources is important to those having responsibility for the administrative and fiscal management of NIH grant awards.

Please e-mail the above requested documents as soon as possible. All documents should either be sent from the Authorized Organizational Representative's e-mail or be accompanied by a cover letter signed by the Authorized Organizational Representative.

Sincerely,

Keturah Williams, M.S.

Grants Management Specialist

Grants Management Branch

National Eye Institute

301-451-2020 (phone)

301-496-9997 (fax)

williamskt@nei.nih.gov

February 19, 2010

Keturah Williams, M.S.
Grants Management Specialist
Grants Management Branch
National Eye Institute

RE: Re: Grant Number: 1 R43 EY 020711 - 01

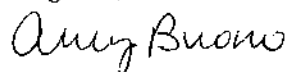
Dear Ms. Williams:

Per your request we are providing the required documents in order to negotiate the award of Grant 1 R43 EY 020711-01 to CalCyte Therapeutics, Inc.

As PI and CalCyte's company official, Dr. Shuyuan Yao will be the primary contact for the NIH to further negotiate this award.

Please contact me at ajbuono@sbcglobal.net if you have any questions.

Regards,



Amy Buono

CalCyte Therapeutics, Inc.
5082 Greenwillow Lane
San Diego, CA 92128

**For New and Renewal Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel**

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. ***Include the principal investigator's name at the top and number consecutively with the rest of the application.*** The sample below is intended to provide guidance regarding the type and extent of information requested.

For instructions and information pertaining to the use of and policy for other support, see Other Support in the PHS 398 Part III, Policies, Assurances, Definitions, and Other Information.

Note effort devoted to projects must now be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

Format

NAME OF INDIVIDUAL

ACTIVE/PENDING

Project Number (Principal Investigator) Source Title of Project (<i>or Subproject</i>)	Dates of Approved/Proposed Project Annual Direct Costs	Person Months (Cal/Academic/ Summer)
The major goals of this project are...		

OVERLAP (*summarized for each individual*)

YAO, Shuyuan

ACTIVE

NONE

PENDING

NONE

OVERLAP

UNIVERSITY OF CALIFORNIA, SAN DIEGO

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA • SANTA CRUZ

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

9500 GILMAN DRIVE
 LA JOLLA, CALIFORNIA 92093-0071
 TEL: (858) 534-6069
 FAX: (858) 534-3478
 EMAIL: IACUC@UCSD.EDU

1/21/2009

APPROVAL LETTER

Principal Investigator: Kang Zhang
 Protocol Number: S09025
 Title: Gene and Genetic Study of Retinal Degeneration
 Species: Rat - Laboratory
 Date Approved: 1/21/2009
 Date Expires: 1/21/2012

The UCSD Institutional Animal Care and Use Committee (IACUC) has approved your Animal Use Protocol.

This is your official approval letter from the IACUC; please print and maintain a copy with your protocol. You may use this approval letter for funding proposal documentation.

Requirements:

- Investigator may not begin using oxygen chamber until the protocol has been amendment to include the location of the chamber. The IACUC recommends calling one of the Animal Welfare Specialists at 534-6069 for a pre-approval once you get your location to speed up the process.
- The following hazard(s) have not been approved by EH&S: (1) -- Other hazard not listed. Please contact Debbie Durand at ddurand@ucsd.edu or 534-6715. Do not begin the proposed animal studies involving these unapproved hazards until you have received EH&S approval.
- A Safety Considerations Meeting is required **before** you begin the animal studies involving: (1) -- Other hazard not listed, (4) Epstein Barr Virus. Replication deficient. Please contact Debbie Durand at ddurand@ucsd.edu or 534-6715 to schedule. A copy of this email has been sent to UCSD Environment, Health and Safety.

It is your responsibility as Principal Investigator to ensure that all members of your laboratory staff have a copy of the protocol and that they understand their individual responsibilities. Your electronic signature on the protocol application indicates that you understand and will comply with all 12 points of the Investigator Assurance below. Please review these assurances now.

Thank you for your cooperation in complying with federal regulations regarding the care and use of laboratory animals: Public Law 99-158, the Health Research Extension Act, and Public Law 99-198, the Animal Welfare Act which is regulated by USDA, APHIS, CFR, Title 9, Parts 1, 2, and 3.

A handwritten signature in black ink, appearing to read "Michael Gorman".

Michael Gorman, Ph.D.
 Chair

Investigator's Assurance
For the Humane Care and Use of Animals Used in Teaching and Research

1. I agree to abide by PHS Policy, USDA Regulations, UCSD policies for the care and use of animals, the provisions of the ILAR Guide to the Care and Use of Laboratory Animals, and all other federal, state, and local laws and regulations governing the use of animals in research.
2. I understand that emergency veterinary care will be administered to animals showing evidence of pain or illness, in addition to routine veterinary care as prescribed for individual species. I understand that it is my responsibility to provide current and updated emergency contact information for personnel who must be contacted in an animal emergency. I understand that any unanticipated pain or distress must be reported to the veterinarian or his/her designee.
3. I assure that I have consulted a veterinarian in the preparation of this proposal, if it includes procedures that could cause pain and distress to a vertebrate animal.
4. I declare that all experiments involving live animals will be performed under my supervision or that of another qualified biomedical scientist listed on this protocol.
5. I certify that all personnel having direct animal contact, including myself, have been trained in humane and scientifically acceptable procedures in animal handling, administration of anesthetics, analgesics, and euthanasia to be used in this project.
6. I certify that all personnel in this project will attend the mandatory Orientation to Research at UCSD class and all other mandatory classes as determined by the Personnel Qualifications Form of each individual.
7. I understand that the use of hazardous agents in animals may only be initiated after approval from EH&S.
8. I certify that all personnel working on this protocol will be given the opportunity to participate in the Medical Monitoring Program at the Center for Occupational and Environmental Medicine (COEM) All personnel on this protocol will be made aware of the hazards involving the use of live animals and tissues.
9. I understand that I must submit an amendment for any proposed changes to this protocol and wait for IACUC approval before beginning the work.
10. I understand that should I use the project described in this application as a basis for a proposal for funding (either extramural or intramural), it is my responsibility to ensure that the description of animal use in such funding proposals are identical in principle to that contained in this application.
11. I understand it is the responsibility of the Principal Investigator to ensure the safe and ethical conduct of all research conducted under this protocol, and to assure that all research is carried out following federal, state, local, and UCSD policies governing animal research.
12. I certify that I will maintain complete, up-to-date and accessible records of procedures on animals as required by policy and regulation.

UNIVERSITY OF CALIFORNIA, SAN DIEGO

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA • SANTA CRUZ

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

9500 GILMAN DRIVE
 LA JOLLA, CALIFORNIA 92093-0071
 TEL: (858) 534-6069
 FAX: (858) 534-3478
 EMAIL: IACUC@UCSD.EDU

7/16/2008

APPROVAL LETTER

Principal Investigator: Kang Zhang
 Protocol Number: S08207
 Title: Gene and Genetic Study of Retinal Degeneration
 Species: Mouse - Laboratory
 Date Approved: 7/16/2008
 Date Expires: 7/16/2011

The UCSD Institutional Animal Care and Use Committee (IACUC) has approved your Animal Use Protocol.

This is your official approval letter from the IACUC; please print and maintain a copy with your protocol. You may use this approval letter for funding proposal documentation.

Requirements:

- The following hazard(s) have not been approved by EH&S: (1) -- Other hazard not listed. Please contact Debbie Durand at ddurand@ucsd.edu or 534-6715. Do not begin the proposed animal studies involving these unapproved hazards until you have received EH&S approval.
- A Safety Considerations Meeting is required **before** you begin the animal studies involving: (1) -- Other hazard not listed, (4) Epstein Barr Virus. Replication deficient. Please contact Debbie Durand at ddurand@ucsd.edu or 534-6715 to schedule. A copy of this email has been sent to UCSD Environment, Health and Safety.

It is your responsibility as Principal Investigator to ensure that all members of your laboratory staff have a copy of the protocol and that they understand their individual responsibilities. Your electronic signature on the protocol application indicates that you understand and will comply with all 12 points of the Investigator Assurance below. Please review these assurances now.

Thank you for your cooperation in complying with federal regulations regarding the care and use of laboratory animals: Public Law 99-158, the Health Research Extension Act, and Public Law 99-198, the Animal Welfare Act which is regulated by USDA, APHIS, CFR, Title 9, Parts 1, 2, and 3.

A handwritten signature in black ink, appearing to read "m gorman".

Michael Gorman, Ph.D.
 Chair

Investigator's Assurance
For the Humane Care and Use of Animals Used in Teaching and Research

1. I agree to abide by PHS Policy, USDA Regulations, UCSD policies for the care and use of animals, the provisions of the ILAR Guide to the Care and Use of Laboratory Animals, and all other federal, state, and local laws and regulations governing the use of animals in research.
2. I understand that emergency veterinary care will be administered to animals showing evidence of pain or illness, in addition to routine veterinary care as prescribed for individual species. I understand that it is my responsibility to provide current and updated emergency contact information for personnel who must be contacted in an animal emergency. I understand that any unanticipated pain or distress must be reported to the veterinarian or his/her designee.
3. I assure that I have consulted a veterinarian in the preparation of this proposal, if it includes procedures that could cause pain and distress to a vertebrate animal.
4. I declare that all experiments involving live animals will be performed under my supervision or that of another qualified biomedical scientist listed on this protocol.
5. I certify that all personnel having direct animal contact, including myself, have been trained in humane and scientifically acceptable procedures in animal handling, administration of anesthetics, analgesics, and euthanasia to be used in this project.
6. I certify that all personnel in this project will attend the mandatory Orientation to Research at UCSD class and all other mandatory classes as determined by the Personnel Qualifications Form of each individual.
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9. I understand that I must submit an amendment for any proposed changes to this protocol and wait for IACUC approval before beginning the work.
10. I understand that should I use the project described in this application as a basis for a proposal for funding (either extramural or intramural), it is my responsibility to ensure that the description of animal use in such funding proposals are identical in principle to that contained in this application.
11. I understand it is the responsibility of the Principal Investigator to ensure the safe and ethical conduct of all research conducted under this protocol, and to assure that all research is carried out following federal, state, local, and UCSD policies governing animal research.
12. I certify that I will maintain complete, up-to-date and accessible records of procedures on animals as required by policy and regulation.

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY**FROM
04/01/2010THROUGH
09/30/2010

List PERSONNEL (Applicant organization only)

Use Cal, Acad, or Summer to Enter Months Devoted to Project

Enter Dollar Amounts Requested (omit cents) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Months	Acad. Months	Summer Months	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	PD/PI							

See Grant Folder for the Revised Subcontract Budget

SUBTOTALS →

CONSULTANT COSTS

EQUIPMENT (Itemize)

SUPPLIES (Itemize by category)

TRAVEL

INPATIENT CARE COSTS

OUTPATIENT CARE COSTS

ALTERATIONS AND RENOVATIONS (Itemize by category)

OTHER EXPENSES (Itemize by category)

The \$5,000 subcontract cost to UCSD is for the animal model experiments. We plan to test the developed cells in 2 animal models and use 30 mice for each model. The cost includes animal fee, animal housing fee, animal operation, monitoring, caring and analysis, etc.

CONSORTIUM/CONTRACTUAL COSTS

DIRECT COSTS 5,000

SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)

\$

CONSORTIUM/CONTRACTUAL COSTS

FACILITIES AND ADMINISTRATIVE COSTS

0

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD

\$



CalCyte Therapeutics, Inc.

5082 Greenwillow Lane
San Diego, CA 92130

Date: Feb 18th, 2010
Subject: NIH fixed fee acceptance

To:
Keturah Williams
Grants Management Specialist
Grants Management Branch
National Eye Institute
301-451-2020(phone)
301-496-9997(fax)

Dear Ms. Williams,

CalCyte Therapeutics, Inc will be happy to accept the 7% fixed fee for our SBIR/STTR applications. We appreciate your assistance and help.

Thanks sincerely,

A handwritten signature in black ink, appearing to read "Shuyuan Yao". The signature is fluid and cursive.

Shuyuan Yao, Ph.D.
Chief Scientific Officer

NIH SMALL BUSINESS INNOVATION RESEARCH PROGRAM
SMALL BUSINESS CONCERN VERIFICATION STATEMENT

Grant Application Number:

1R43EY020711-01

Organization:

CalCyte Therapeutics, Inc.

Project Director(s)/Principal Investigator(s) (PD(s)/PI(s)):

Shuyuan Yao

The Small Business Innovation Research (SBIR) program legislation requires that the applicant small business concern (SBC) be eligible at the time of the award. As the responsible Federal staff for administering NIH grant funds, Grants Management Officials of the NIH Institutes and Centers (ICs) must verify eligibility prior to issuing a Notice of Grant Award. If the SBC is affiliated with any other organization (domestic or foreign), see www.sba.gov/size.

If an application is selected for funding under the SBIR program, no award will be issued until the NIH IC receives and accepts the following information, which may be provided in a format of your choosing or by completing a checklist as in the example below:

- ☒ 1 The above-named organization is a for-profit United States SBC that is at least 51% owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States, or in the case of a publicly-owned business, at least 51% of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.

or

The above-named organization is a for-profit business concern that is at least 51% owned and controlled by another (one) for-profit business concern that is at least 51% owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States.

Complete the following part of (1) if relevant: If the above-named applicant organization has been determined by the Small Business Administration (SBA) to be "other than small" for a size standard of not more than 500 employees or for purposes of the SBIR program:

Have you been recertified by SBA?

☐ Yes

☒ No

If not recertified, have you requested a recertification by SBA for eligibility under the SBIR program?

☐ Yes

☒ No

- ☒ 2 The above-named organization is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, has, including its affiliates, 500 or fewer employees, is not involved in a merger/acquisition that is near complete, and meets the other regulatory requirements found in Title 13, Code of Federal Regulations (CFR), Part 121. (Note that the SBA considers "agreements to merge (including agreements in principle) to have present effect on the power to control a concern" [Section 121.103(d)(1) of 13 CFR 121]).
- ☒ 3 The *research space* occupied by the above-named organization is available to and under the control of the above-named organization *for the conduct of its portion of the proposed project*.
- ☒ 4 All research on the above-referenced grant will be *performed in its entirety* in the United States, unless otherwise approved by the Grants Management Officer prior to issuance of an award.
- ☒ 5 The above-named PD's/PI's *primary employment* is with the above-named organization and more than one-half of the above-named PD's/PI's time will be in the employ of the above-named organization at the time of award and for the duration of the project, unless otherwise approved by the Grants Management Officer prior to issuance of an award. For Multiple PD/PI projects, the Contact PD/PI meets the primary employment requirement.
- ☒ 6 It is understood that the Public Health Service will not support any *market research* under its SBIR program (see "Definitions," SBIR/STTR SF424 (R&R) Application Guide) or literature searches that will lead to a new or expanded statement of work, and that if an award is made, any such costs, if requested in the application, will be removed prior to award.
- ☒ 7 It is understood that if this project is funded, drawing NIH award funds from the HHS Payment Management System serves as certification that the above-named organization has in place written policies and procedures for financial and business management systems that comply with 45 CFR 74 and the NIH Grants Policy Statement (12/03) and will follow those policies and procedures.

My signature is verification that the statements checked (☒) above are true and complete. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

(Official Authorized to Sign for the Organization)

SHUYUAN YAO

(Date)

02/10/2010

Williams, Keturah (NIH/NEI) [E]

From: Shuyuan Yao [REDACTED]
Sent: Tuesday, February 23, 2010 3:10 PM
To: Williams, Keturah (NIH/NEI) [E]
Cc: kang zhang; Sheng Ding; Amy and John Buono
Subject: Re: Grant Number: 1 R43 EY 020711 - 01 PI: Shuyuan Yao
Follow Up Flag: Follow up
Flag Status: Completed
Attachments: financial management system questionnaire format.pdf

Dear Keturah,

Attached please find the Financial Management System Questionnaire prepared by CalCyte Therapeutics, Inc accounting personnel. If any further information is need, please let me know.

Thanks sincerely,

Shuyuan Yao
CalCyte Therapeutics, Inc.
[REDACTED]

2/25/2010



CalCyte Therapeutics, Inc.
5082 Greenwillow Lane
San Diego, CA 92130

EVALUATION OF FINANCIAL MANAGEMENT SYSTEMS (Abbreviated Questionnaire)			
	YES	NO	COMMENT
A. ACCOUNTING SYSTEM:			
1. Is there a chart of accounts?	Yes		The CalCyte accounting system is a double entry fully computerized system using commercially available software. The CalCyte chart of accounts will be set up to provide for project level accounting and tracking of project expenditures relative to project budgets.
2. Does the accounting system include a project cost ledger providing for the recording of expenditures for each program by required budget cost categories?	Yes		The accounting software and supporting schedules will allow for tracking of the SBIR Grant against planned project budgetary items. The accounting software will be utilized by CalCyte for tax reporting, profit and loss statements, cash flow analysis, balance sheet analysis and reporting, and project level accounting.
3. How do employees account for their time and effort? Please explain.			CalCyte employees will account for time on a weekly basis utilizing project defined categories of activities so that labor can be tracked against project budgets and schedules. Monthly payrolls will be developed through the compilation of these project level hourly time sheets and processed by a commercial payroll service.
B. FINANCIAL CAPABILITY:			
1. Does the organization prepare financial statements at least annually? (Provide a copy of latest Balance Sheet and Income Statement.)	Yes		CalCyte will generate monthly Income Statements and Balance Sheet reports utilizing its computerized accounting system
2. Has the organization established line(s) of credit? If so, identify source and amount.		No	CalCyte has not developed lines of credit at this time. Current financing is based upon equity contributions, grants and research contracts. Management believes that it will be necessary to continue this type of financing until research results and additional equity



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			contributions create the financial strength necessary for the Company to develop lines of credit.
C. BUDGETARY CONTROLS:			
1. Are there budgetary controls in effect (e.g. comparison of budget with actual expenditures on a monthly basis) to preclude drawing down federal funds in excess of:	Yes		
a. Total funds authorized on the Notice of Grant Award;			CalCyte's financial reporting system provides for the necessary monitoring of project cash flow to ensure that project (SBIR) milestones are reached within budgetary and time limits. The only backstop to the SBIR funds will be at risk equity of management, an incentive to remain on time and within budget. Financial reports will be finalized on a monthly basis and updated on a weekly basis for management reporting to ensure project financial solvency.
b. Total funds available for any cost category if restricted on the Notice of Grant Award.			All financial reports and analyses will be done on a line item basis to ensure that all project activities are fully funded as necessary during the project. Management will review project updates on a weekly basis to ensure solvency and will take necessary budgetary actions on at least a monthly basis to ensure that all project expenditures are appropriately monitored to ensure project success within budget.
D. INTERNAL CONTROLS			
1. What safeguards has the grantee instituted to ensure adequate internal controls in the company? Please describe. Some examples might be:			
a. Accounting entries are supported by appropriate documentation; e.g. purchase orders and vouchers.			Purchase orders will be initiated at the project level and must be approved by administrative and management



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		<p>personnel. Expenditure approval levels will be developed commensurate with the project budget to ensure that the project will be administratively efficient but fiscally prudent with regards to third party expenditures. No third party expenditure will be allowed utilizing SBIR funds that does not have at least two CalCyte signatures of approval on a purchase order.</p>
b. Separation of responsibility in the receipt, payment, and recording of cash.		<p>All project purchases will be made subject to appropriate purchase orders approved at the project and administrative level to ensure compliance with budget and availability of cash for payment. Checks in excess of an appropriate level will require two approved signatures. Check writing and accounting functions will be separated to ensure that at least two individuals with administrative or management authority have knowledge and control of all CalCyte purchases.</p>
c. Other		<p>Upon notice of the award of an SBIR grant, CalCyte will determine the exact accounting system it intends to utilize and will develop sample Charts of Account, Balance Sheets, Income Statements, Cash Flow and Project Monitoring reports. These reports will be available to appropriate Office of Extramural Research personnel upon request.</p>